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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,040	07/21/1999	PETER MOSE LARSEN	2012.0390004	9201

7590 11/05/2002

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/05/2002 21

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/297,040

Applicant(s)

MOSE LARSEN ET AL.

Examiner

David J. Steadman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

Claims 1-27 are pending in the application.

Applicants' election of the invention of Group II in Paper No. 12, filed 09/12/01, and further election of the invention of IEF 614 – ATP synthase beta chain (see page 54 of the instant specification) in Paper No. 19, filed 08/26/02, is acknowledged.

The instant Office action is a supplemental lack of unity requirement. The previous Office action of Paper No. 6 was a lack of unity requirement of pending claims 1-27. It is noted that claims 12 and 13 were inadvertently omitted from the claim groupings. Applicants responded in Paper No. 8 by electing with traverse the invention of Group II claims 7-11. In order to clarify the record, a supplemental lack of unity (Paper No. 10) was mailed that included claims 12 and 13 and further required an election of a single protein as listed in Tables 1 and 2. Applicants responded in Paper No. 12 by electing with traverse the invention of Group II, claims 7-11. Applicants did not elect a single protein from Tables 1 and 2 in Paper No. 12. A Letter of Non-Response (Paper No. 17) was mailed to applicant requesting election of a single protein listed in Tables 1 and 2. Applicants responded (Paper No. 19) by electing with traverse the invention of IEF 614 as listed on page 54 of the instant specification. The instant supplemental lack of unity requirement is at the discretion of the examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in light of the improper grouping of claim 6, drawn to a diabetes-mediating protein, with the invention of Group I, drawn to an in vivo method for identifying a diabetes-mediating protein.

### ***Lack of Unity***

1. Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claim(s) 1-5, drawn to an in vivo method for identifying a diabetes-mediated protein.

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- II. Claim(s) 6-11, 19, 22, and 23, drawn to a diabetes-mediating protein and a method of treating or preventing diabetes or a diabetes-related disorder, by administering a diabetes-mediating protein capable of preventing or delaying the development of diabetes in a subject.
  - III. Claim(s) 12 and 13, drawn to a method for predicting the development of diabetes.
  - IV. Claim(s) 14, drawn to an in vitro method of identifying a protective or deleterious diabetes-mediating protein.
  - V. Claim(s) 15 and 16, drawn to a transgenic non-human mammal comprising an exogenous diabetes-mediating protein transgene and a method of use of a transgenic mammal expressing a diabetes-mediating protein for identifying a protective or deleterious diabetes-mediating protein.
  - VI. Claim(s) 17, drawn to an assay for screening compounds that are capable of effecting expression of a diabetes-mediating protein using a transgenic mammal.
  - VII. Claim(s) 18, drawn to a compound that is capable of effecting expression of a diabetes-mediating protein.
  - VIII. Claim(s) 19, 20, and 24-26, drawn to a method of treating or preventing diabetes or a diabetes-related disorder by administering a compound or an antisense compound capable of preventing or delaying the development of diabetes in a subject.
  - IX. Claim(s) 19, 21, 24, 25, drawn to a method of treating or preventing diabetes or a diabetes-related disorder by administering a compound or an antibody capable of preventing or delaying the development of diabetes in a subject.
  - X. Claim(s) 27, drawn to a method of identifying a compound capable of modulating the activity of a diabetes-mediating protein.
2. If applicant should elect the invention of Group II or III, applicant is further required under 35 U.S.C. 121 and 372 to elect a single invention from the proteins listed in Tables 1 and 2.

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3. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

- a. the methods of Groups I, III, IV, VI, and VIII-X comprise unrelated steps, utilize unrelated products, and/or yield different results;
- b. the protein of Group II, the transgenic mammal of Group V, and the compound of Group VII are unrelated and chemically distinct entities;
- c. the protein of Group II and the compound of Group VII is neither used nor made by the methods of Groups I, III, IV, VI, or VIII-X; and
- d. the transgenic mammal of Group V is neither made nor used by the methods of Groups I, III, IV, and VIII-X and Group V already includes a method of use of a transgenic mammal that comprises unrelated steps to the method of Group VI and 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention.

4. The inventions listed as Groups I-X share no technical relationship for the reasons given above and therefore, unity of invention does not exist and a lack of unity is required.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

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David J. Steadman, Ph.D.  
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Art Unit 1652

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